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10/748,154	12/31/2003	David Siever	49425	6977

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EXAMINER
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GEDEON, BRIAN T

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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09/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/748,154

Applicant(s)

SIEVER, DAVID

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. This action is in response to the amendment after non-final filed 5 July 2007.

Claims 1-3, 6-12, and 15-20 remain pending.

### ***Terminal Disclaimer***

2. The Terminal Disclaimer filed 5 July 2007 has been approved.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Timmerman et al. ("Effects of 20-min audio-visual stimulation (AVS) at dominant alpha frequency and twice dominant alpha frequency on the cortical EEG"; International Journal of Psychophysiology Volume 32, Issue 1 , 1 April 1999, Pages 55-61).

In regard to claim 6, Timmerman et al. discloses a process comprising: (a) obtaining a frequency of brain waves in a brain (page 3 last paragraph); and (b) stimulating the brain at the twice measured frequency (page 4 first paragraph).

In regard to claim 7, Timmerman et al. discloses a process according to claim 6 wherein the frequency of stimulation in step (b) is in the range of 16-24 Hz based on the aberrant brain wave frequency in the brain being in the range of 8-12 Hz (page 6). The examiner takes the position that since the ranges disclosed by Timmerman et al. encompass the values claimed there would be sufficient specificity for the ranges to anticipate the applicant's values for stimulation. See MPEP 2131.03

5. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Siever (US Patent no. 5,709,645).

In regard to claim 9, Siever discloses a photic stimulator that stimulates the left hemisphere of the brain at a first frequency, and stimulates the right hemisphere of the brain at a second frequency, wherein the first frequency differs from the second frequency between 0.1 Hz and 3 Hz (Col 4 lines 31-67).

In regard to claims 10 and 11, the device and method of Siever is capable of stimulating the hemispheres of the brain with beta frequencies of 12-15 Hz and alpha frequencies between 5-9 Hz, Table 1. Further, Siever suggests applying a stimulation frequency between 7-10 Hz for generating an abundance of sensory stimulation that reduces the internal chatter of a busy or stressed subject's mind in order to elicit a meditative or hypnotic response, or to elicit lucid dreams, (Col 4 lines 54-67).

In regard to claim 12, Siever teaches and suggests using delta frequencies between 1-4 Hz, Table 1.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siever (US Patent no. 5,709,645) in view of Chuprikov et al. et al. (US Patent no. 5,137,018).

In regard to claims 1 and 18, Chuprikov et al. disclose a method of stimulating the left hemisphere of the brain and the right hemisphere of the brain by exposing the right halves of both eyes of a patient to light at one wavelength of light and exposing the left halves of both eyes to light at a different wavelength (Col 5 lines 1-34 & Col 14 lines 40-57). Chuprikov et al. also disclose that before that step that the both halves of each eye are exposed to a different wavelength (Col 5 lines 36-56 & Col 12 lines 48-55). Finally Chuprikov et al. shows that the steps can be repeated (Claim 1 (e)). Chuprikov et al. disclose also that the left hemisphere is stimulated when the right visual fields are stimulated and that the right hemisphere is stimulated when the left visual fields are stimulated (Col 12 lines 6-11). However, Chuprikov et al. fail to teach the desired frequency ranges for stimulation. Siever describes a photic stimulator that simulates the left hemisphere of the brain with a frequency of 15-20, while simultaneously or separately stimulating the right hemisphere with a frequency of 12-15 Hz, col 4 lines 36-40. The device is also capable of stimulating with an alpha frequency in the range of 8-12 Hz, see Table 1. Siever teaches that stimulation frequencies in this range allow for

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treatment of ADD (i.e., hyperactivity disorder) in adolescent children (Col 4 lines 36-40).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Chuprikov et al. with the frequency ranges of Siever since Siever teaches that the discloses ranges, which encompass the ranges as claimed, are effective for treating hyperactive disorder using photic stimulation.

Further, it would not be beyond one of ordinary skill to be able to implement a time delay, of an optimum range, between applications of steps since it has been held that where general working conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

In regard to claims 2 and 19, Chuprikov et al. imply in his disclosure that the period of time for the first stimulation portion is equal to the period for the second stimulation portion of the process (Col 5 lines 31-34 & lines 57-60).

In regard to claims 3 and 20, Chuprikov et al. disclose that the period of time in which the light stimulation is given to a patient should be in the range of time of 2-10 minutes (Col 2 lines 20-21 & Col 11 lines 22-23).

Further in regard to claim 2, 3, 19, and 20, it has been held in that where the general working conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Timmerman et al. as applied to claim 6 above.

With respect to claim 8, Timmerman et al. discloses the claimed invention except for the specific values of stimulating frequency, and the corresponding brain wave frequency. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the specific values of stimulating frequency, and the corresponding brain wave frequency, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

9. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorges (US Patent no. 4,314,502).

In regard to claim 15, Gorges discloses a photic and auditory stimulation method for pacing breathing in a subject to a predetermined breathing rate in the range of from 5 to 7 breath cycles per minute, the process comprising: (a) exposing the subject to an auditory cue (Col 2 Lines 24-25); and (b) simultaneously exposing the subject to various stimulation frequencies or combinations of frequencies (Col 2 lines 40-46). While Gorges does not specifically state that the method is used for pacing breathing, Gorges discloses that the method is used to relax a patient, which would imply an alteration into the breathing rate of an individual. Furthermore, Gorges states that various areas of the brain can be stimulated with the disclosed process (Col 7 lines 31-32). One of ordinary skill in the art would recognize that using the aforementioned process one could stimulate the medulla oblongata, the portion of the brain that controls breathing rate, which has been established by scientific research, at a rate that would stimulate a breathing rate of 5-7 cycles per minute by routine trial and error.

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In regard to claim 16, Gorges discloses a method according to claim 15 wherein the auditory cue is a synthesized heart beat sound (Col 3 lines 3-7).

In regard to claim 17, Gorges discloses a method according to claim 15, wherein the auditory cue is can be provided at from two to four times the predetermined breathing rate (Col 3 lines 3-7).

### ***Response to Arguments***

10. Applicant's arguments filed 26 June 2007 with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection made above and in view of the cancellation of claims 4 and 5.

11. Applicant's arguments filed 26 June 2007 with respect to claims 6-8 have been fully considered but they are not persuasive. The Timmerman reference suggests to one of ordinary skill in the art to obtain a dominant brain frequency in the range of <1-32 Hz, and then to stimulate at twice the dominant alpha frequency, page 1 3<sup>rd</sup> paragraph. Aberrant brain waves, at the frequency (i.e., 10Hz) as claimed, are necessarily obtained and stimulated against since the range of frequencies obtained by Timmerman encompass the frequency as claimed, and Timmerman provides the teaching for stimulating at twice the dominant frequency within that range. Furthermore, to address Applicant's argument that "twice alpha stimulation significantly increased theta, beta 1, beta 2 brain activity," the Examiner respectfully submits that unexpected results cannot overcome a 102 rejection.



**“Evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejection and thus cannot overcome a rejection.” MPEP 2131.04**

The Examiner submits that the steps of claims 6-8 are sufficiently taught by the Timmerman reference.

12. Applicant's arguments filed 26 June 2007 with respect to claims 9-12 have been considered but are moot in view of the new ground(s) of rejection made above.

13. Applicant's arguments filed 26 June 2007 with respect to claims 15-17 have been fully considered but they are not persuasive. In regard to claims 15 and 16, the Examiner submits that the Gorges reference substantially teaches (a) exposing the subject to an auditory cue (Col 2 Lines 24-25); and (b) simultaneously exposing the subject to various stimulation frequencies or combinations of frequencies (Col 2 lines 40-46). The auditory cue is also a heartbeat sound (Col. 6 lines 31-44). The method for pacing breathing in a subject to a predetermined breathing rate in the range of from 5 to 7 breath cycles per minute, recited in the preamble of claim 15, has no limiting value since it merely describe functional language. Furthermore, Gorges states that various areas of the brain can be stimulated with the disclosed process (Col 7 lines 31-32). One of ordinary skill in the art would recognize that using the aforementioned process one could stimulate the medulla oblongata, the portion of the brain that controls breathing rate, which has been established by scientific research, at a rate that would stimulate a breathing rate of 5-7 cycles per minute by routine trial and error.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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